HED NEWS

Week Ending
5/17/19
Bill Zerfas, Editor

For the Office Director

**** SENSITIVE – NOT FOR DISTRIBUTION ****

Pre-Submission Meeting for Pyraclonil. Members of HED, RD and EFED attended a pre-submission meeting with representatives from Nichino America to discuss the new pesticide active ingredient, pyraclonil. Pyraclonil is a Carbonitrile herbicide with a new mode-of-action for control of watergrass in rice and preemergence control on multiple sedge species and broadleaf weeds. The submission will include US registration on rice and is planned for submission in Q4 2019. (Thurston Morton, 703-305-6691)

Meeting with MITC Taskforce to Discuss Cancer Assessment. On May 8, 2019, HED and PRD staff met with MITC registrants to discuss comments submitted in response to the draft MITC human health risk assessment for registration review. The focus of the meeting was the discussion of cancer-related comments and presentation of additional information that the MITC Taskforce would like HED to consider for the cancer assessment of MITC~~, which in turn may have an impact in the risk assessment for this chemical~~. The Taskforce will submit the additional information presented, and HED will consider it; in addition to the public comments submitted, to determine whether a revision of the cancer assessment for MITC is needed. (Evisabel Craig, 703-347-0108)

Conference Call with Syngenta to Discuss SAP Report and Preparation for Particle Size Distribution Meeting. On May 16, 2019 HED and PRD held the second, in a series of bi-weekly conference calls with representatives from Syngenta on the Scientific Advisory Panel (SAP) panel report on a new approach methodology (NAM) to refine inhalation risk assessments. As part of this NAM, particle size distributions (PSDs) for different exposure scenarios are needed, and a meeting to help inform this issue and determine a path forward has been scheduled for June 2019. HED and Syngenta discussed potential experts to invite to the meeting. Additionally, HED answered questions regarding response documents that will be drafted in response to the SAP report over the next few months by OPP and Syngenta. (Monique Perron, 703-347-0395)

HESI/ETS Sponsored Thyroid Hormone Assessment Workshop. Sarah Gallagher and Liz Mèndez from HED attended a workshop on the implications of thyroid hormone assessments for developmental and reproductive toxicology. The meeting was sponsored by the Health and Environmental Sciences Institute (HESI) and the European Teratology Society (ETS). The goal of the meeting was to bring together scientists from academia, industry and regulatory authorities to:

1) discuss the state-of-the-science on thyroid hormone assessments;
2) identify knowledge gaps as it relates to regulatory developmental and reproduction toxicity testing;
3) provide clarification and guidance regarding the collection (timing and methods), assessment (standardization and validation), and interpretation of thyroid hormone data; and
4) discuss recommendations on ways to improve data interpretation/understanding of thyroid changes and their relationship to adverse outcomes.

In addition, participants discussed the approaches to thyroid hormone assessment requirements, interpretation, and regulatory impacts across different jurisdictions. (Liz Mèndez 703-305-5453)

Monthly Teleconference with California DPR. HED participated in a monthly coordination conference call with California DPR. The topics included:

- the carbaryl dermal absorption factor;
- California's proposed cancelation of chlorpyrifos
- DPR staff visits for the FIFRA SAP meeting in June
- the fipronil comparative thyroid assay; and
- the status of OPP's cancer classification review for 1,3-dichloropropene.

During the call, HED agreed to provide feedback on CalDPR's proposed dermal absorption factor for carbaryl and provide some literature references on thyroid hormones. (Sarah Gallagher, 703-347-0431)

Conference of the Parties Meeting for Three International Conventions. Representatives from EPA, including Monique Perron from HED, and the Department of State attended the Conference of the Parties (COP) for the Rotterdam, Stockholm, and Basel Conventions in Geneva, Switzerland. The Rotterdam Convention evaluates banned or severely restricted pesticides for inclusion on a Prior Informed Consent (PIC) list to promote shared responsibility and cooperative efforts in the international trade of these chemicals. The Stockholm Convention evaluates chemicals and requires parties to take measures to eliminate or reduce the release of persistent organic pollutants (POPs). The Basel Convention aims to reduce the generation and restrict the transboundary movement of hazardous wastes. Staff from OCSPP attended the

Rotterdam and Stockholm COP meetings, while staff from OLEM attended the Basel COP meeting. A wide range of industrial and pesticide chemicals and policy issues were discussed across the three Conventions where the U.S. delegation provided an integral role in aiding negotiations and providing technical advice to help parties reach consensus. For the Rotterdam Convention, phorate and hexabromocyclododecane (HBCD) were listed; however, consensus was not reached for acetochlor, carbosulfan, fenthion formulation, paraquat formulation, and chrysotile asbestos. Consequently, these chemicals and formulations were not listed and will be considered at the next COP meeting in 2021. For the Stockholm Convention, dicofol was listed without specific exemptions. PFOA, its salts, and related chemicals was also listed with specific exemptions. (Monique Perron, 703-347-0395)

Technical Guidance to Bayer Animal Health on Enhanced Pet Spot-On Adverse Reporting. TEB and RD staff met with Bayer to discuss their work on providing enhanced adverse event data on their portfolio of pet spot-on products. Bayer has begun submitting quarterly enhanced adverse event and sales data using OPP's enhanced reporting templates and was looking for technical guidance from TEB on the use of the OPP reporting templates. Bayer is planning to submit additional quarterly reports and will change their reporting frequency from quarterly to annual when TEB has confirmed that they are using the reporting templates accurately and consistently for their pet products. (Aaron Niman, 703-347-8184)

Chemical	Deliverable	Branch
Difenoconazole	Human Health Risk Assessment	RAB IV
Pydiflumetofen	Human Health Risk Assessment	RAB IV
Uniconazole-P	Human Health Risk Assessment	RAB II
Clofentezine	Human Health Risk Assessment	RAB VI
Cyflufenamid	Label Amendment Review	RAB III

For HED

RAB IV Completed DRAFT Human Health Risk Assessment for Difenoconazole. Difenoconazole is a broad-spectrum fungicide belonging to the triazole group of fungicides proposed for new foliar uses on vegetable, root, subgroup 1A and vegetable, leaves of root and tuber, group 2 and the establishment of a

tolerance with no U.S. registration for dried tea. No new residential uses were proposed. Toxicological endpoints remained unchanged. Dietary, aggregate, occupational handler and occupational post-application exposure and risk assessments were updated. No dietary, residential, aggregate, or occupational post-application risks of concern were identified. Several occupational handler exposure scenarios were of concern at baseline attire, the minimum attire required across all proposed labels; however, additional personal protective equipment (PPE; i.e., gloves) results in no risks of concern for the occupational handler. The RAB IV Difenoconazole Risk Assessment Team includes: Bonnie Cropp-Kohlligian (Residue Chemistry and Risk Assessment), Thurston Morton (Dietary), Brian Van Deusen (ORE), and Connor Williams (Toxicology). (Bonnie Cropp-Kohlligian, 703-305-7462).

RAB IV Completed DRAFT Human Health Risk Assessment for Pydiflumetofen. Pydiflumetofen is a pyrazole carboxamide fungicide proposed for new foliar uses on a number of crops and new seed treatment uses on rapeseed crop subgroup 20A and soybean and registration of a new seed treatment end-use product. No new residential uses were proposed. Toxicological endpoints remained unchanged. Dietary, aggregate, occupational handler and occupational post-application exposure and risk assessments were updated. No dietary, residential, aggregate, occupational handler, or occupational post-application risks of concern were identified. The RAB IV Pydiflumetofen Risk Assessment Team includes: Bonnie Cropp-Kohlligian (Risk Assessment), Thurston Morton and Janet Camp (Residue Chemistry and Dietary), Wade Britton (ORE), and Austin Wray (Toxicology). (Bonnie Cropp-Kohlligian, 703-305-7462)

RAB II Completed Draft Human Health Risk Assessment for Uniconazole-P. RAB II completed a reg review risk assessment for uniconazole-P, a plant growth regulator registered for use on ornamental plants and fruiting vegetables. Screening level acute and chronic aggregate (food only) dietary exposure analyses were conducted, as well as a quantitative assessment for dermal and inhalation occupational handler and occupational post-application exposures. Acute and dietary exposure risk estimates are below HED's level of concern for the general U.S. population and all population subgroups. There were also no risk estimates of concern for occupational handlers. (Emily Rogers, 703-347-0678)

RAB VI Completed Human Health Risk Assessment for Clofentezine. Clofentezine is an acaricide that is registered for application to a variety of field crops and for uses on commercial ornamentals in greenhouses, outdoor containers, and field-grown nursery stock. RAB VI completed a draft human health risk assessment for the new use on guava. There are no residential uses for this chemical. There are no dietary risks of concern, nor any occupational risks of concern. (Sheila Piper, 703-308-2717)

RAB III Completed Amended Label Review for Cyflufenamid. RAB III completed an assessment for a label amendment for cyflufenamid product, Miltrex® 10 SC Fungicide (EPA Reg. No. 8033-103). The label amendment proposed to decrease the number of applications per year (from two to one), double the application rate (from 0.022 lb ai/A to 0.44 lb ai/A), and to extend the pre-harvest interval (from 3 days to 7 days) for small fruit vine climbing, except kiwifruit, subgroup 13-07F. The review included residue chemistry data and an evaluation of the potential occupational exposure. RAB III recommended in favor of the label amendment. (Bill Wassell, 703-305-6135)